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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/421,545	10/20/1999	GREGORY R. MUNDY	432722002621	4287

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EXAMINER

GITOMER, RALPH J

ART UNIT	PAPER NUMBER
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1651

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DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/421,545

Applicant(s)

Mundy et al.

Examiner

Ralph Gitomer

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 6, 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 5-7, and 19-23 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5-7, 19, 22, and 23 is/are rejected.
- 7) ☒ Claim(s) 20 and 21 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). 18
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 6) ☐ Other:

The finality of the rejection made 3/6/2003 is hereby withdrawn and a new Office Action follows. The amendment received 5/6/2003 has been entered and claims 1, 5-7, 19-23 are currently pending in this application. The Terminal Disclaimer received 11/27/2002 has been accepted. The new abstract must be presented on a separate page and has not been received. Please update the status of related applications in the specification in the standard format. The IDS's received 3/14/2000 and 9/10/2001 have been considered.

The rejection of record under 35 USC 112, first paragraph, is hereby withdrawn.

Priority is claimed to 7/10/1998. Please inform the examiner as to how the present application differs from the two parent applications, 09/361,775 and 09/113,947 to properly confirm the claimed priority date of 7/10/98. And please inform the examiner of any related cases, pending, allowed or abandoned.

The request for correction of inventor name is accepted. However, the new declaration containing Rossini's full name is not signed by Mundy.

Claims 20 and 21 would be allowable if written in independent form.

The submission of about 85 references received at various times in various files is noted, however it would appear the references are directed toward non-analogous art. None appear to be directed to hair growth treated by any of the classes of claimed compounds. The Applicants are invited to particularly point out any references which may be either specifically analogous or definitely pertinent to the claimed invention. Note 24 USPQ2d Golden Valley Microwave Foods Inc. v. Weaver Popcorn Co. Inc. where the patent applicant has duty not just to disclose prior art reference but to make disclosure in such way as not to "bury" it within other disclosures of less relevant prior art.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification fails to provide written description for the presently claimed ~~peptidyl~~ aldehyde.

This application contains sequence disclosures at page 29, lines 8 and 9, and at the penultimate line on page 37, that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for one or more of the reasons set forth on

the attached form ~~§~~ Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequences and/or Amino Acid Sequence Disclosures~~§~~. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) *for the response to this action to be complete.*

Claim 5 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

In claim 5, ~~§~~ post-plastic surgery~~§~~ is indefinite regarding what sort of condition may be intended.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5-7, 19, 22-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Tanihara.

Tanihara (JP 6025288), English translation provided, entitled ~~§~~ Novel Peptides with Transforming Growth Factor Beta Activity: Useful for Treating Wounds, Osteoporosis, Rheumatoid Arthritis, etc.~~§~~ teaches in the English abstract, peptidyl

aldehydes for treating osteoporosis. Specifically, N-(tert-butoxycarbonyl)-O-benzyl-L-serine is taught for that function. On page 14 of the translation, fluoride may also be administered simultaneously as an anti-resorptive agent.

5 All the features of the claims are taught by Tanihara for the same function as claimed.

The following prior art pertinent to applicant's disclosure is made of record and not relied upon:

10 Lin (5,726,319) teaches dipeptide analogs to release growth hormone.

Chatterjee (5,852,007) teaches protease inhibitors to treat bone resorption that are peptidyl aldehydes.

15 Takeda (JP 5294826) teaches peptidyl aldehydes for treating osteoporosis.

Aibe (WO 98 01133) teaches in the abstract, peptidyl aldehydes to treat osteoporosis.

Higuchi (5,395,824) entitled ~~XXXX~~Dipeptide Derivative and Prophylactic and Therapeutic Agent for Bone Diseases Containing the Same~~XXXX~~ teaches in claim 1, a peptidyl aldehyde for inhibiting
20 loss of calcium from bones. In column 2 first paragraph, the object of the invention is to provide a compound for the prevention or treatment of bone resorption diseases.

Sohda (5,498,728) entitled ~~XXXX~~Derivatives of L-Tryptophanal and
25 Their Use as Medicinals~~XXXX~~ teaches in column 2 first paragraph, the

object of the invention is to provide drugs to suppress bone resorption. Claim 1 teaches a peptidyl aldehyde.

Kiso (EP 0 504 938 A3) teaches in the abstract, a peptidyl aldehyde for preventing or treating osteoporosis.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm. The examiner can also be reached on alternate Mondays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (703) 308-4743. The fax phone number for this Art Unit is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235. For 24 hour access to patent application information 7 days per week, or for filing applications electronically, please visit our website at www.uspto.gov and click on the button Patent Electronic Business Center for more information.

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